TCT-388

Multi-slice Computer Tomography Analysis of Percutaneous Ventricular Restoration (PVR) using the Parachute Device in Patients with Heart Failure Post Anterior Wall Myocardial Infarction: First-In-Man Experience

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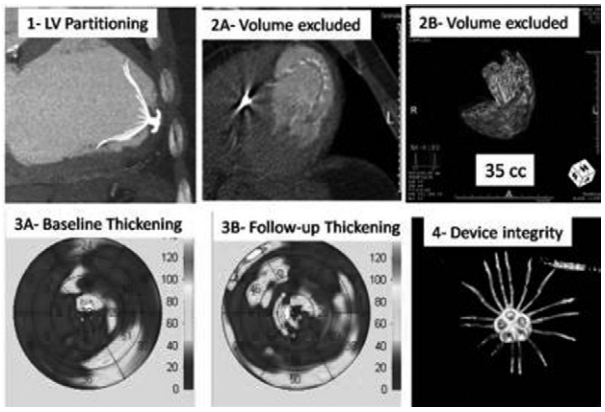
Background: Left ventricle (LV) remodeling leads to increased LV volumes and CHF with high morbidity and mortality. Treatment options are limited. We aim to evaluate acute success and 6-month geometric outcomes of percutaneous ventricular restoration (PVR) with a novel percutaneous LV partitioning device, Parachute TM (Figure), by Computer Tomography (CT).
Methods: 74 pts with CHF NYHA class II-IV, 15-40% EF after antero-apical MI without revascularization options, were enrolled in 14 sites. Parachute was deployed into the LV apex to partition off the damaged myocardium. Baseline gated CT with 10% incremental reconstruction was obtained in all pts for device sizing and procedure guidance. 20 pts underwent 6 months CT follow-up with planar and 3D volumetric quantification of LV geometry, partitioned volume, global and regional function and device integrity (Figure). Analysis was done by an independent corelab.
Results: Baseline CT of first 25 pts showed extensive LV calcification and cavity/device perimeter ratio at the landing zone (>0.8) as potential mechanisms for poor device anchoring in 2 cases. Excluded volume was 39.8±11.9ml. EF was 27±10% pre procedure and 32±15% at follow-up (p=NS). Segmental analysis showed a trend to increase basal segments (AHA 1-6) function (myocardium thickening 25.3±10.5 vs. 39.4±25.3-mm p=0.09). Thrombus formed in the excluded volume in 23% of cases. There were no device fractures. Complete analysis will be available for presentation.
Conclusions: Comprehensive CT allows safe pt screening for PVR. Follow-up CT provides insights into mechanism of action and safety of this novel therapy.



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Acute and 6-Month Clinical and Echocardiographic Outcomes of the First-In-Human Experiences with the Implantation of a Novel Catheter-based Ventricular Partitioning Device in Patients with Ischemic Heart Failure and Dilated Left Ventricle

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Background: Anterior wall myocardial infarction leads to left ventricle (LV) remodeling, increased LV volumes, myocardial stress and ultimately congestive heart failure (CHF). The safety of percutaneous ventricular restoration (PVR) using a novel percutaneous LV partitioning device constructed of fluoropolymer (ePTFE) membrane stretched over a nitinol frame and developed to improve cardiac performance through reduction of LV volumes was shown to be safe in a small cohort of patients.To evaluate acute and 6-month outcomes of the pooled first-in-human (FIH Cohort A and B) and U.S. feasibility trials testing PVR using the Parachute TM device.
Methods: A total of 75 patients with CHF class II-IV (NYHA) due to anterior wall MI with akinetic or dyskinetic wall motion abnormality, ejection fraction 15-40% and without revascularization options underwent PVR with the Parachute device. All events were adjudicated and CT, EKG and echo data were analyzed by independent core labs. The device is deployed into the apex of the left ventricle and partitions off the damaged myocardium. To date 46 patients have completed 6-month follow-up. Serial echocardiography showed significant reduction in LV end-diastole (127.5cc vs 106.7cc) and end-systole (93.8cc vs 75.3cc) volumes. There were no strokes and the incidence of cardiac death was 4.3% (2/46). Stroke volume and heart rates were unchanged from baseline. Complete adjudicated 6-month outcomes of 61 patients will be available for presentation.
Results: To date 46 patients have completed 6-month follow-up. Serial echocardiography showed significant reduction in LV end-diastole (127.5cc vs 106.7cc) and end-systole (93.8cc vs 75.3cc) volumes. There were no strokes and the incidence of cardiac death was 4.3% (2/46). Stroke volume and heart rates were unchanged from baseline. Complete adjudicated 6-month outcomes of 61 patients will be available for presentation.
Conclusions: The preliminary FIH results demonstrate the safety of PVR using the Parachute device. Expanded echo and clinical outcomes will be presented and provide further insights into mechanism and effectiveness of this novel therapy for patients with ischemic CHF.

TCT-390

Outcome Of The Impella Device for Acute Mechanical Circulatory Support

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Background: Acute cardiogenic shock is associated with high mortality rates. Mechanical circulatory devices have been increasingly used in this setting for hemodynamic support. The Impella device (Abiomed Inc., Danvers, MA) is a microaxial LVAD that can be inserted using a less invasive technique. The purpose of this study is to determine the outcome of patients who have undergone the placement of the Impella device for acute cardiogenic shock in our institution.
Methods: We performed a retrospective chart review of 47 consecutive patients with cardiogenic shock who underwent placement of the Impella device between February 6st, 2006 and December 31st, 2011. Charts were evaluated for demographics, operative details and postoperative outcomes. Operative mortality was defined as death within 30-days of surgery.
Results: The average age of the patients was 60.23 ±13 and the majority of the patients were male (N=33). The indication for placement of the Impella device

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